REMARKS

Status of the Claims

Claims 1-10, 13 and 14 are pending in the present application. Claims 11 and 12 are canceled. Claim 1 has been amended. Claims 1-4, 8-10, 13 and 14 are rejected. Claims 5-7 are free of the prior art and would be allowable of rewritten to overcome the rejection under 35 U.S.C. 112. See paragraph 10 of the Office Action.

Rejection of Claims 1-10 under 35 U.S.C. § 112, second paragraph (Page 3, Paragraph 5 of the Office Action)

The Examiner rejects claims 1-10 under 35 U.S.C. § 112, second paragraph. Applicants respectfully traverse the rejection of the pending claims. Reconsideration and withdrawal of the instant rejection are respectfully requested.

The Examiner asserts that claim 1 is indefinite in being incomplete for omitting essential structural and functional cooperative relationships of elements. Specifically, the Examiner alleges that claim 1 is unclear as to how the distinguished and counted unagglutinated insoluble carrier particles, agglutinated insoluble carrier particles, and blood cells, correlate to the elements. Accordingly, Applicants have amended step (d) of claim 1 as follows:

> (d) distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells from the intensity of the scattered lights detected in the step (b), in reference to the first and second threshold values set in the step (c),so as to assay the target antigen or the target antibody present based on the counted agglutinated insoluble carrier particles.

This amendment is non-narrowing in nature and serves only to clarify claim language. Based on the above, Applicants respectfully submit that the claims particularly point out and distinctly claim

the subject matter of the present invention. Withdrawal of the instant rejection is therefore respectfully requested.

Rejection of Claims 13 and 14 under 35 U.S.C. § 102(b) (Pages 3-4, Paragraph 6 of the Office Action)

The Examiner rejects claims 13 and 14 under 35 U.S.C. § 102(b) for allegedly being anticipated by Kosako '714 (U.S. Patent 5,527,714). Applicants respectfully traverse. Reconsideration and withdrawal of the instant rejection are requested.

The Present Invention

The present invention as recited in claim 13 relates to an immunoassay apparatus for assaying target antigen or target antibody present in a serum component or a blood plasma component of a whole blood sample, comprising:

a reaction part for mixing a whole blood sample with insoluble carrier particles which are sensitized with an antigen or antibody and have a different size than that of blood cells, to cause an immune agglutination reaction resulting in an immune agglutination reaction mixture comprising agglutinated insoluble carrier particles and unagglutinated insoluble carrier particles;

a dispensing mechanism for introducing the resulting immune agglutination reaction mixture to a flow cell,

a laser for irradiating the particles passing through the flow cell with laser light,

a photo acceptance unit for detecting scattered light generated thereby,

signal processing means for converting the scattered light to an electrical signal, and

data processing means for setting a first threshold value for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles and a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells with regard to signal based on intensity of the scattered light; and for distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells according to the set first and second threshold values.

U.S. Patent 5,527,714 to Kosako

Kosako discloses obtaining a corrected size distribution of particles that are to be measured. This corrected size distribution of particles that are to be measured are obtained by first estimating the size distribution of the particles which are not measured along the entire range from the size distribution of the particles not to be measured to the determined range by means of a spline function. Then, the estimated size distribution of the particles not to be measured are subtracted from the total particle size distribution.

Distinctions Between the Present Invention and Kosako

Contrary to the position taken by the Examiner, Kosako does not disclose "insoluble carrier particles which are sensitized with an antigen or antibody and have a different size than that of blood cells," [e.g. "a reaction part for mixing a whole blood sample with insoluble carrier particles which are sensitized with an antigen or antibody and have a different size than that of blood cells, to cause an immune agglutination reaction resulting in an immune agglutination reaction mixture comprising agglutinated insoluble carrier particles and unagglutinated insoluble carrier particles."]

Further, Kosako does not disclose "a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells." Thus, Kosako is silent with respect to "data processing means for setting a first threshold value for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles and a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells with regard to signal based on intensity of the scattered light; and for distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells according to the set first and second threshold values."

Significantly, "blood cells" are not distinguished or counted in Kosako.

Accordingly, claims 13 and 14 are not anticipated by Kosako since these claims have structural distinctions from the disclosure of Kosako with respect to the reaction part and the data processing means. Because of these structural distinctions, using the immunoassay apparatus recited in claim 13, the skilled artisan can perform a highly accurate immunoassay on a whole blood sample without the need to hemolyze the whole blood sample or separate serum therefrom, as described on page 4, lines 21-24, of the specification. On the other hand, Kosako '714 does not disclose an immunoassay apparatus wherein an immunoassay can be carried out with a whole blood sample, as acknowledged by the Examiner on page 9 of the Office Action. For these reasons, Kosako '714 fail to disclose each and every limitation of the instant claims. As such, Kosako '714 fail to anticipate the present invention under 35 U.S.C. § 102(b). Withdrawal of the instant rejection is therefore respectfully requested.

Rejection of Claims 1-4, 9 and 10 under 35 U.S.C. § 103(a) (Pages 5-6, Paragraph 7 of the Office Action)

Kosako '714 in view of Moskowitz et al.

The Examiner rejects claims 1-4, 9 and 10 under 35 U.S.C. § 103(a) for allegedly being obvious over Kosako '714 in view of Moskowitz et al. Applicants respectfully traverse the rejection of the pending claims. Reconsideration and withdrawal of the instant rejection are respectfully requested.

The Present Invention

The present invention as recited in claim 1 relates to an immunoassay for assaying target antigen or target antibody present in a serum component or a blood plasma component of a whole blood sample, comprising the steps of:

(a) mixing a whole blood sample with insoluble carrier particles which are sensitized with an antigen or antibody and have a different size than that of blood cells, to cause an immune agglutination reaction resulting in an immune agglutination reaction mixture comprising agglutinated insoluble carrier particles and unagglutinated insoluble carrier particles;

(b) introducing the immune agglutination reaction mixture to a flow cell, irradiating the particles passing through the flow cell with laser light, and detecting scattered lights generated thereby;

(c) setting a first threshold value for distinguishing unagglutinated insoluble carrier particles from agglutinated insoluble carrier particles and a second threshold value for distinguishing the agglutinated insoluble carrier particles from blood cells with regard to intensity of the scattered light; and

(d) distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells from the intensity of the scattered light detected in the step (b), in reference to the first and second threshold values set in the step (c), so as to assay the target antigen or the target antibody present based on the counted agglutinated insoluble carrier particles.

Distinctions Between the Present Invention and Kosako in view of Moskowitz et al.

The above-mentioned comments with respect to Kosako are herein incorporated by reference.

Kosako does not disclose or suggest distinguishing and counting blood cells.

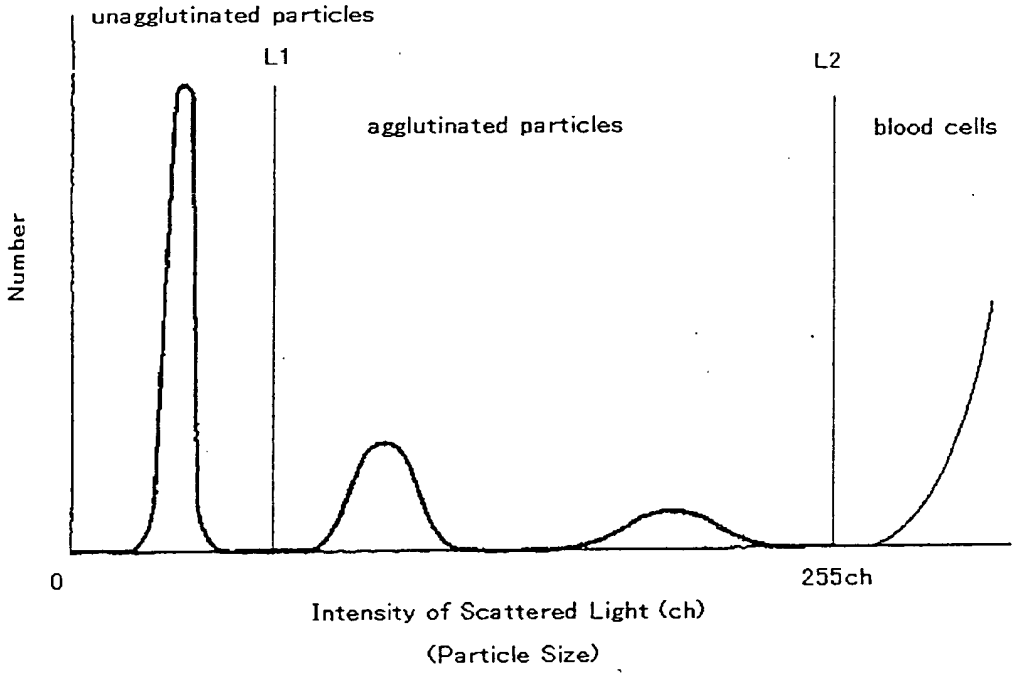
Kosako further differs from the present invention since it fails to disclose distinguishing and counting the unagglutinated insoluble carrier particles, the agglutinated insoluble carrier particles and the blood cells. Thus, it is not possible to carry out an immunoassay without hemolyzing the whole blood sample or separating serum therefrom based on the teachings of Kosako.

Moreover, Moskowitz et al. discloses an immunoassay in which platelets are counted by combining fibrinogen bound particles and a sample containing platelets. Because platelets have the ability to bind to fibrinogen, platelets can aggregate. As a control, fibrinogen bound particles, an antibody for fibrinogen and platelets, which do not have the ability to bind fibrinogen, are combined. Therefore, one control value is measured in the Moskowtiz et al. immunoassay. Further, Moskowitz et al. do not disclose distinguishing and counting the blood cells.

In contrast to the teachings of the cited prior art, two threshold values are claimed in the present invention. These claimed two threshold values are set in order to distinguish the unagglutinated insoluble particles and the agglutinated insoluble particles as well as the agglutinated insoluble particles and blood cells. See Fig. 3 of the present specification, which is reproduced below for the Examiner's convenience.

Particle Size Distribution

FIG. 3



The claimed threshold values are set by measuring the scattered light in step (b) of claim 1. This feature of the claimed invention is neither disclosed nor suggested by the combined teachings of Kosako and Moskowitz et al. Thus, the rejection of claims 1-4, 9 and 10 under 35 U.S.C. § 103(a) as being obvious over Kosako '714 in view of Moskowitz et al. should be withdrawn by the Examiner.

Rejection of Claim 8 under 35 U.S.C. § 103(a) (Page 7, Paragraph 8 of the Office Action)

Kosako '714 in view of Moskowitz et al. and further in view of Steel '351

The Examiner also rejects claim 8 under 35 U.S.C. § 103(a) for allegedly being obvious over Kosako '714 in view of Moskowitz et al. and further in view of Steel '351 (WO 98/20351). Applicants respectfully traverse. Reconsideration and withdrawal of the instant rejection are respectfully requested.

The Present Invention

The present invention as recited in claim 8 further defines the immunoassay according to claim 1, wherein the scattered light is forward scattered light.

Distinctions Between the Present Invention and Kosako in view of Moskowitz et al. and further in view of Steel

The above-mentioned comments with respect to Kosako and Moskowitz et al. are herein incorporated by reference.

The Examiner relies on Steel '351 to teach forward scattered light. However, as noted above, Kosako '714 in view of Moskowitz et al. fail to render the claims of the present application obvious. Steel '351 merely teaches forward scattered light and does not make up for the deficiencies of Kosako '714 and Moskowitz et al. As such, the instant claims are not obvious under 35 U.S.C. § 103(a) over Kosako '714 in view of Moskowitz et al. and further in view of Steel '351. Withdrawal of the instant rejection is therefore respectfully requested.

Conclusion

Applicants respectfully submit that the above remarks and/or amendments fully address and overcome the outstanding rejections and objections. For the foregoing reasons, Applicants respectfully request the Examiner to withdraw all of the outstanding rejections and to issue a Notice of Allowance indicating the patentability of the present claims. Early and favorable action of the merits of the present application is thereby respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By 

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